Clinical trial results:
Arthrose érosive des doigts : traitement par méthotrexate versus placebo- évaluation de l'action clinique et structurale (IRM dédiée)- Etude ADEM

Summary

EudraCT number	2007-005437-11
Trial protocol	FR
Global end of trial date	15 October 2018

Results information

Result version number	v1 (current)
This version publication date	28 July 2022
First version publication date	28 July 2022

Trial information

Trial identification

Sponsor protocol code	06-API-07

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	chu de nice
Sponsor organisation address	DRCI-Hôpital de Cimiez - 4 avenue reine victoria, Nice, France, 06003
Public contact	Coordination Investigator , Pr Roux , +33 492039220, roux.c@chu-nice.fr
Scientific contact	Coordination Investigator , Pr Roux , +33 492039220, roux.c@chu-nice.fr

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 October 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 October 2018
Global end of trial reached?	Yes
Global end of trial date	15 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

DEMONSTRATE THAT TREATMENT WITH METHOTREXATE IS MORE EFFICIENT ON PAIN THAT PLACEBO AFTER 3 MONTHS

Protection of trial subjects:

The patients signed an informed consent and were recruited into the Rheumatology Department of the CHU d e Nice

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 May 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 64
Worldwide total number of subjects	64
EEA total number of subjects	64

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	64
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The patients are screening in the rhumatology.

Pre-assignment

Screening details:

The period is the inclusion period

Pre-assignment period milestones

Number of subjects started	64
Number of subjects completed	64

Period 1

Period 1 title	Inclusion Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Arm title	Méthotrexate or placebo
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Methotrexate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intramuscular use

Dosage and administration details:

10 mg/week during 6 weeks

Number of subjects in period 1	Méthotrexate or placebo
Started	64
Completed	64

Baseline characteristics

End points

End points reporting groups

Reporting group title	Méthotrexate or placebo

Reporting group description: -

Primary: Pain measured by EVA at 3 months

End point title	Pain measured by EVA at 3 months[1]

End point description:

End point type	Primary

End point timeframe:

at 3 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses is in the communication

End point values	Méthotrexate or placebo			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: EVA	64			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
At each visit	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.1

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: There are no non serious adverse events

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 November 2009	Selection Criteria
12 November 2009	Add Questionnary
04 February 2010	Add evaluation adiponectine

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported